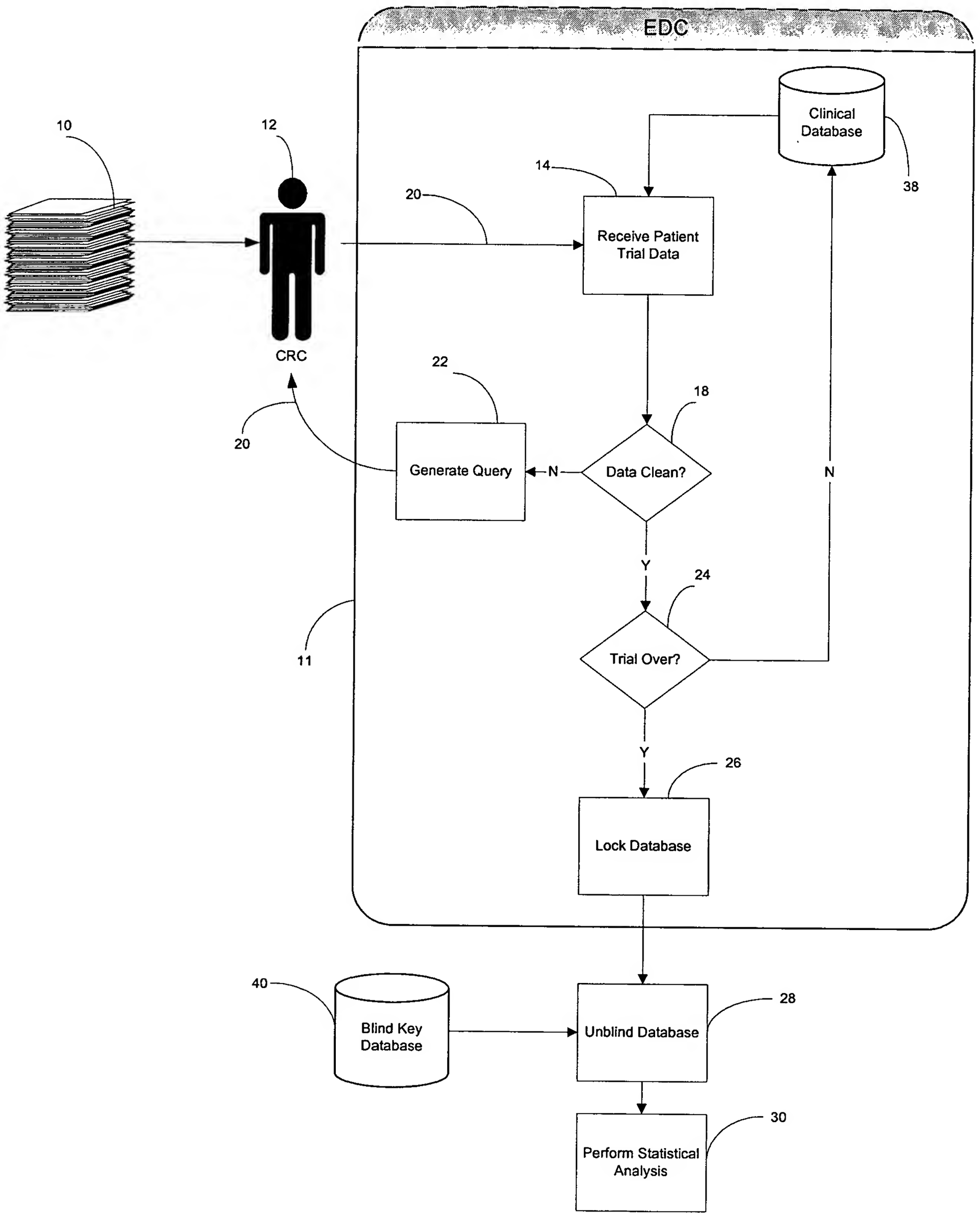
EDC
10
12
CRC
20
22
Generate Query
N
18
Data Clean?
N
Y
24
Trial Over?
N
Y
11
14
20
Receive Patient Trial Data
Clinical Database
38
26
Lock Database
40
Blind Key Database
28
Unblind Database
30
Perform Statistical Analysis

FIG. 1

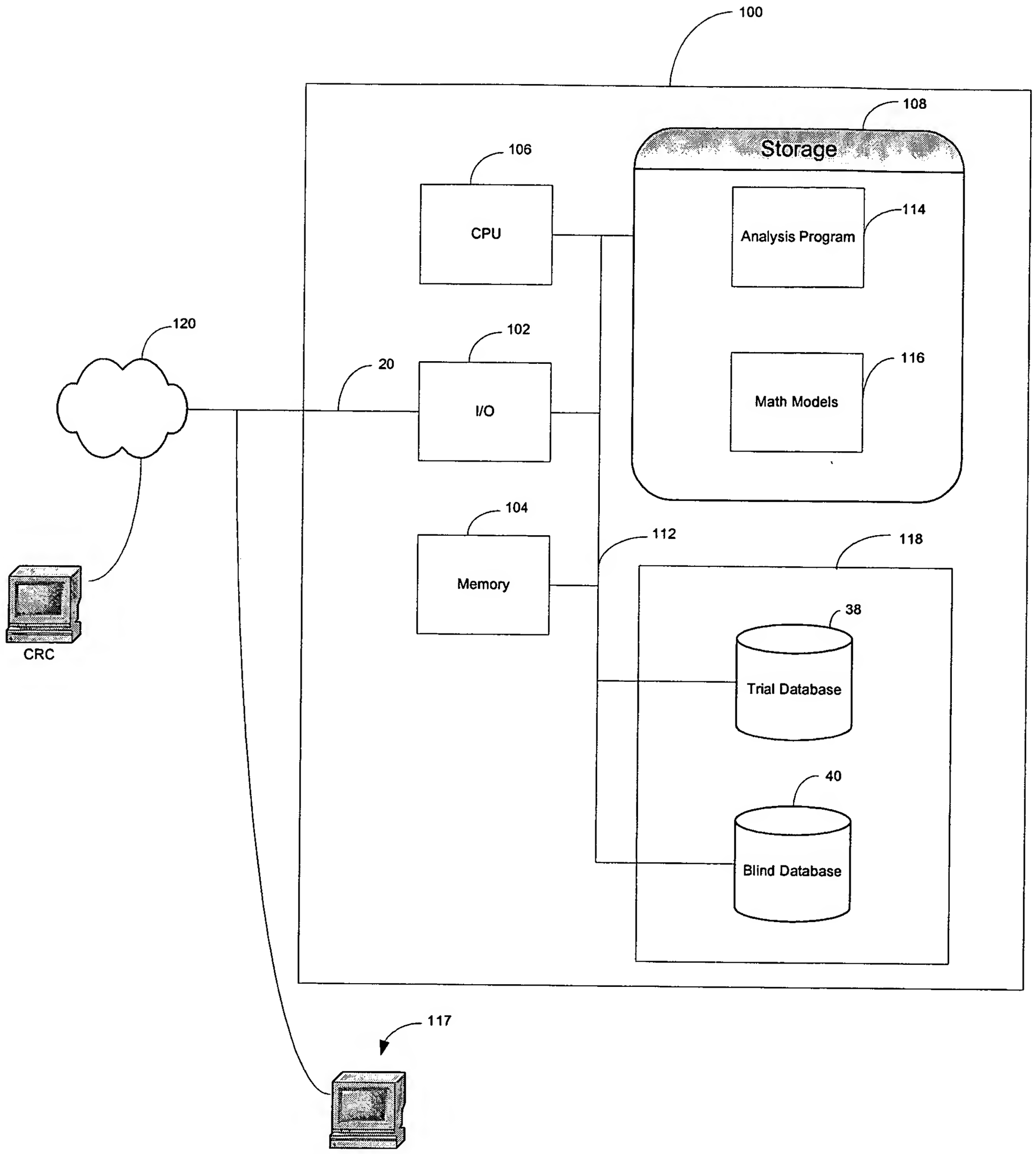
100
108
Storage
106
CPU
114
Analysis Program
120
102
20
I/O
116
Math Models
104
112
118
Memory
38
Trial Database
40
Blind Database
CRC
117

FIG. 2

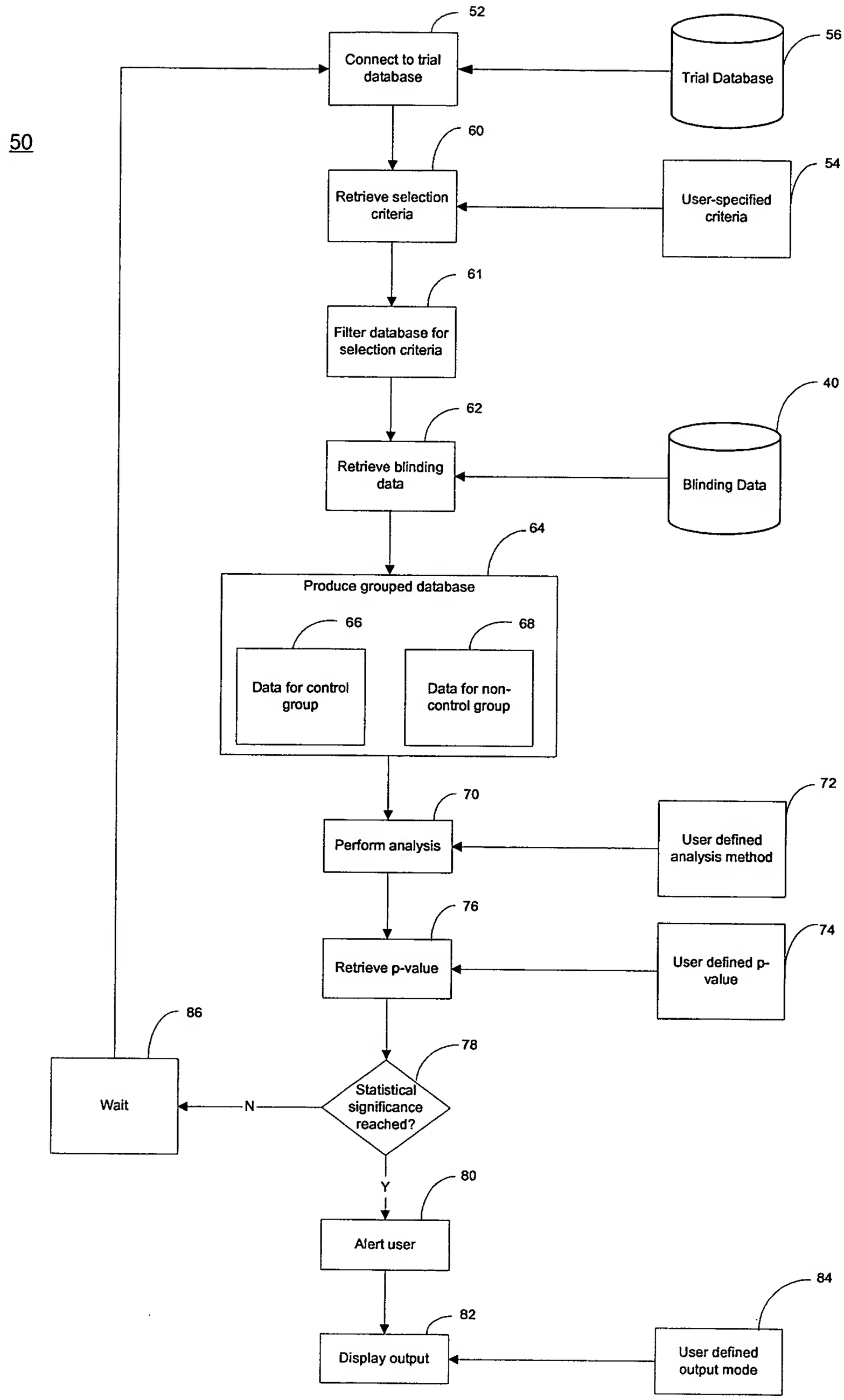
50
52
Connect to trial database
Trial Database
56
60
Retrieve selection criteria
User-specified criteria
54
61
Filter database for selection criteria
40
62
Retrieve blinding data
Blinding Data
64
Produce grouped database
66
Data for control group
68
Data for non-control group
70
Perform analysis
User defined analysis method
72
76
Retrieve p-value
User defined p-value
74
86
Wait
78
Statistical significance reached?
N
Y
80
Alert user
82
Display output
User defined output mode
84

FIG. 3

40

Subject ID	Study Arm
101	A
102	A
103	B
104	A
105	B
106	A
107	B
108	B
109	B
110	A
111	B
112	A
113	A
114	A
115	B
116	A
117	B
118	A
119	B
120	B
121	B
122	A
123	B
124	A
125	A

FIG. 4

Subject ID	Heart Attack? 0=No 1=Yes
101	0
102	1
103	1
104	0
105	1
106	0
107	1
108	0
109	0
110	0
111	1
112	0
113	0
114	1
115	1
116	0
117	1
118	0
119	1
120	1
121	0
122	0
123	1
124	0
125	0

FIG. 5

Subject ID	Study Arm	Heart Attack? 0=No 1=Yes
101	A	0
102	A	1
103	B	1
104	A	0
105	B	1
106	A	0
107	B	1
108	B	0
109	B	0
110	A	0
111	B	1
112	A	0
113	A	0
114	A	1
115	B	1
116	A	0
117	B	1
118	A	0
119	B	1
120	B	1
121	B	0
122	A	0
123	B	1
124	A	0
125	A	0

FIG. 6

Subject ID	Data Status	Heart Attack? 0=No 1=Yes
101	1	0
102	5	1
103	5	1
104	4	0
105	5	1
106	5	0
107	1	Y
108	5	0
109	5	0
110	4	0
111	5	1
112	3	0
113	5	0
114	1	Still evaluating patient for heart attack
115	5	1
116	5	0
117	5	1
118	1	Don't know
119	5	1
120	5	1
121	5	0
122	4	0
123	3	1
124	5	0
125	5	0

Key

1	Queries Open
2	Pending Review
3	Pending SDV
4	Pending Lock
5	Locked

FIG. 7A

Subject ID	Data Status	Heart Attack? 0=No 1=Yes
102	5	1
103	5	1
104	4	0
105	5	1
106	5	0
108	5	0
109	5	0
110	4	0
111	5	1
112	3	0
113	5	0
115	5	1
116	5	0
117	5	1
119	5	1
120	5	1
121	5	0
122	4	0
123	3	1
124	5	0
125	5	0

Key

1	Queries Open
2	Pending Review
3	Pending SDV
4	Pending Lock
5	Locked

FIG. 7B

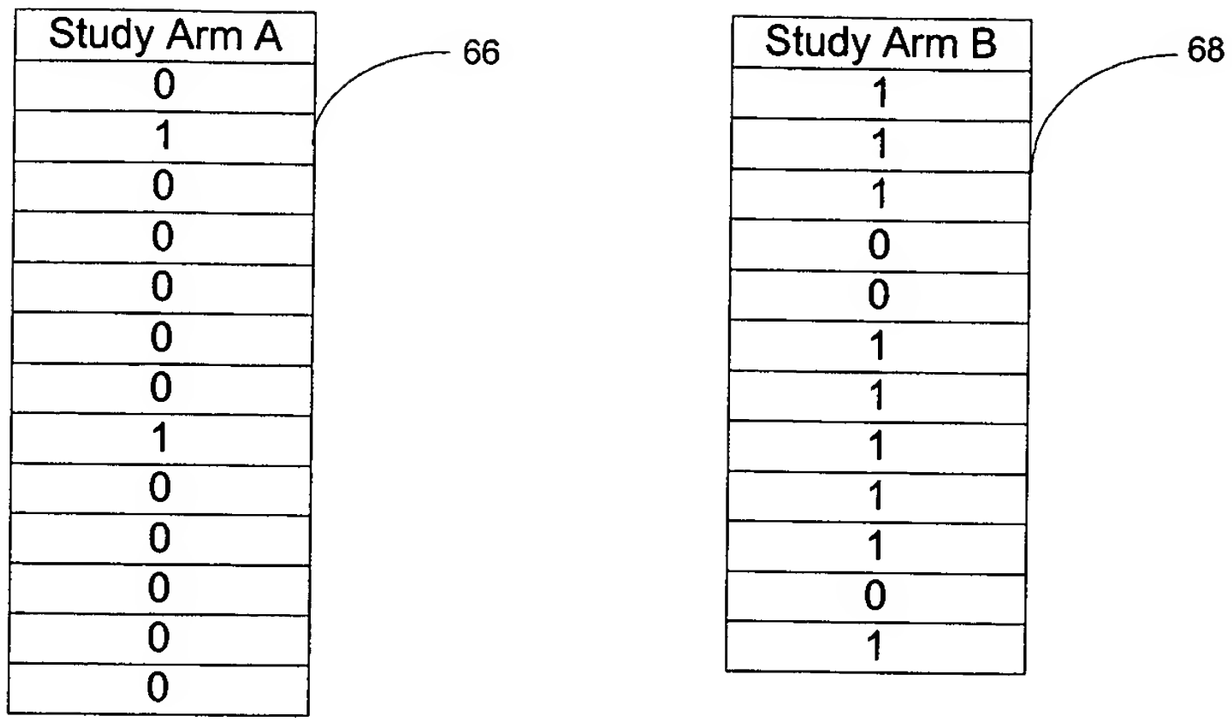

FIG. 8